European legislation
Impact on the scientific use of animals

ANIMPACT: Mapping European diversity under Directive 2010/63/EU and proposing tools to increase dialogue

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Greater harmonization in terms of uniform regulation of research with animals, including uniform animal welfare standards, was an important objective in revising European legislation. Technical harmonization is facilitated by the revised and expanded Directive, but Member States (MS) still have flexibility in establishing mechanisms under the Directive. The ANIMPACT project is mapping ethical and practical aspects of the legal framework, with focus on decision-making over animal experiments.

The ANIMPACT project addresses how Directive 2010/63/EU interacts with research by looking at decision-making mechanisms. These include regulatory mechanisms external to research (legal norms and the licensing process, ethical norms and the ethical review process), mechanisms internal to research (how the 3Rs are considered in peer review, how researchers select animal species) and the intersection of the two (how researchers perceive regulation and how their work is impacted by it). The emerging results show considerable diversity, in particular in systems for project evaluation and authorization of animal experiments. The aspects that the project evaluation is to include (e. g. predicted benefit, 3Rs compliance, severity, harm-benefit analysis) are established by the Directive and subsequent endorsed guidelines. However, there is a lot of room for interpretation of key concepts such as "predicted benefit" and "harm-benefit analysis". Furthermore where and by whom projects are evaluated is left to individual MS to determine. The result is a wide variation in approaches. Depending on the MS, a project may be evaluated by a national, regional or institutional committee, by people with varying scientific and other expertise, with or without the involvement of lay members / special interest groups. To this procedural diversity should be added the diversity in outcome expected because of the mentioned room left for interpretation left in the hands of differently composed groups of people. Plous and Herzog (2001) found that institutional animal care and use committees in the US (thus in the same country and under the same guidance) took widely different decisions over the same animal protocol. The total number of committees in the EU is not known, but considering that at least 15 Member States have regional, local and / or institutional committees, they are expected to be several hundred. More than detailed guidance, we argue that these committees need mechanisms for dialogue in order to avoid a situation where similar protocols are evaluated very differently by different committees. One such approach may be to regularly publish commented case studies, such as the Protocol Review column in the journal Lab Animal. We are presently exploring ways of establishing a European equivalent. At the conference

we will also invite an open discussion of potential formats and mechanisms to create discussion fora for entities involved in project evaluation across the EU.

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